

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION**

TRUTEK CORP.,

Plaintiff,

v.

Case No. 2:21-cv-10312

BLUEWILLOW BIOLOGICS, INC.;
ROBIN ROE 1 through 10, gender
neutral fictitious names, and; ABC
CORPORATION 1 through 10 (fictitious
names).

Hon. F. Kay Behm

Defendants.

**DEFENDANT/COUNTER-PLAINTIFF BLUEWILLOW
BIOLOGICS, INC.'S REPLY BRIEF IN SUPPORT OF MOTION TO
EXCLUDE THE EXPERT REPORTS AND TESTIMONY OF
ALEXEI ERMAKOV AND SHANE BURNS**

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I. INTRODUCTION

Trutek provides no concrete evidence for why Ermakov's and Burns's testing and related testimony should not be excluded. Rather than citing substantive evidence disclosed during discovery to demonstrate reliability, Trutek resorts to unsupported attorney argument and a new declaration from a different expert, Dr. Lemmo. When considering reliability, courts should consider:

- (1) whether a theory or technique can be (and has been) tested,
- (2) whether the theory or technique has been subjected to peer review and publication, (3) the known or potential rate of error in using a particular scientific technique and the existence and maintenance of standards controlling the technique's operation, and (4) whether the theory or technique has been generally accepted in the particular scientific field.

Smelser v. Norfolk S. Ry., 105 F.3d 299, 303 (6th Cir. 1997) (citing *Glaser v. Thompson Medical Co., Inc.*, 32 F.3d 969, 972 (6th Cir.1994)). An "expert's bald assurance of validity is not enough." *Id.*

II. ARGUMENT

A. Trutek Is Not Permitted to Introduce New Evidence to Support the Reliability of Ermakov's and Burns's Testing and Methods

First, the only thing that is "confusing" is Trutek's misunderstanding of the purpose of expert reports in patent litigation. ECF 71 at 13. Fed. R. Civ. P. 37(c)(1) states "If a party fails to provide information . . . as required by Rule 26(a) or (e), the party is not allowed to use that information . . . to supply evidence on a motion, at a hearing, or at trial" Rule 26(e) requires an expert report with "a complete

statement of *all the opinions the witness will express* and the basis and reasons for them.”¹ At trial, expert witnesses are *only* allowed to testify about opinions in their reports; the reports define the limit of testimony.

Second, much of Trutek’s Response is premised on information contained in Dr. Lemmo’s new declaration. ECF 71-4. Most of that information was not disclosed in Lemmo’s earlier reports and should not be considered. *See Davis v. Brouse McDowell, L.P.A.*, 596 F.3d 1355, 1362 (Fed. Cir. 2010) (applying Sixth Circuit precedent and finding district court did not abuse its discretion striking portion of expert declaration filed in support of summary judgment motion that went beyond scope of earlier-filed report or was inconsistent with deposition testimony). “The exclusion of non-disclosed evidence is automatic and mandatory under Rule 37(c)(1) unless non-disclosure was justified or harmless.” *Dickenson v. Cardiac & Thoracic Surgery of E. Tenn.*, 388 F.3d 976, 983 (6th Cir. 2004) (internal citation omitted). At least paragraphs 14-20, 22-27, 29-31, 33, and 35 of Dr. Lemmo’s declaration contain information he did not include and/or is

¹ Trutek says it will bring a witness to trial to identify and describe the preparation of the samples used in the “blind test[s]” run by Ermakov and Burns. ECF 71 at 14. Rule 26(A)(1) requires a party to disclose this information during discovery and, because it forms the basis for its experts’ opinions, it is improper and prejudicial for Trutek to wait until trial to disclose this information. Further, Burns’s deposition directly contradicts Trutek’s assertion that these individuals played no part in the testing. ECF 57-6 (Burns Tr. at 51:7-52:6). Burns was the observer; the mystery Trutek employees prepared the samples and pig skin substrate.

contradicted by his earlier reports and deposition. Trutek offers no justification for why it did not previously disclose this information or explain why Lemmo is defending the testing.² Nor is the non-disclosure harmless as BlueWillow could not have examined Dr. Lemmo on the new information when he was deposed.

B. Ermakov's and Burns's Testing and Methods Are Irrelevant and Unreliable

Trutek takes an extremely limited (and incorrect) view of whether the methods (and the expert's qualifications for performing the methods) were designed solely for purposes of litigation. The relevant question is not whether the methods were designed for "this lawsuit" (ECF 71 at 10). Indeed, Trutek admits that Ermakov's apparatus was developed specifically for litigation filed by Trutek. ECF 71 at 11, 17. Even Ermakov admitted the testing was "different from, like, anything else [he] ha[d] done before." ECF 57-4 (Ermakov Tr. at 68:5-8). Trutek also admits Ermakov's test was not peer reviewed (ECF 71 at 13) and offers no evidence the technique has been tested, has a known error rate, or that it is generally accepted in the relevant field for the purpose for which it was used here.

² Trutek offers no explanation for why Lemmo is qualified to speak to the validity or reliability of these tests. Indeed, Lemmo admitted during deposition that he relied on the Burns and Ermakov testing when reaching his infringement opinions without confirming their qualifications, without having any role in designing the test conditions, without confirming the soundness of their testing methodology, and without confirming the identity of, or manufacturing and expiration date, of any of the samples. ECF 59 at 21; ECF 59-5 (Peterson Decl., Ex. 7) (Lemmo Tr.) at 227:3-228:13, 229:17-230:3, 231:19-232:15.

See Smelser, 105 F.3d at 303. Trutek’s assertion that Ermakov’s test results were “sound and logical” is nothing but unsupported attorney argument. ECF 71 at 13.

Trutek’s assertions regarding Burns’s testing are also flawed. Trutek argues he followed “well established published procedures” but does not describe or provide those procedures. ECF 71 at 13. In fact, Burns admitted during deposition that while he “tr[ie]d to imitate . . . common industry standards,” most of the standards did not apply to tests with a gel or liquid. ECF 57-6 at 94:1-6. He also stated there are no industry standards for measuring electrostatic charge on pigskin. *Id.* at 94:7-11. While his equipment is standard, it was not used in a standard manner. *Id.* at 94:1-98:18. Trutek also claims Burns’s testing was reviewed by a disinterested party (ECF 71 at 13), but does not identify the individual or context, falling well short of showing the method was subject to peer review or publication.

There is no legitimate dispute that Ermakov’s and Burns’s test methods were designed specifically for Trutek to evaluate products in connection with the ’802 patent, and Trutek offers no evidence they have been used by any other company or for any other purpose. One factor courts should consider when evaluating an expert’s testimony is “whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying.” *See Smelser*, 105 F.3d at 303 (citing *Daubert v. Merrell Dow*

Pharmaceuticals, Inc. (on Remand), 43 F.3d 1311, 1317 (9th Cir.1995), *cert. denied*, 516 U.S. 869 (1995)). Only the former is evidence that the testing and related opinions comport with dictates of good science. *Smelser*, 105 F.3d at 303.

Trutek's assertion that the Burns report from 2019 is from "entirely different substances" is not supported by the record. ECF 71 at 2, 14. Indeed, Lemmo confirmed "the formulation and composition of all the Trutek NasalGuard products are the same." ECF 59-5 (Peterson Decl., Ex. 7) (Lemmo Tr.) at 36:16-21. Trutek cites no evidence to rebut this testimony or to support the alleged formulation change or if it is even material to the intended purpose for the testing. ECF 71 at 14.

The remainder of Trutek's Response is unsupported attorney argument. Trutek attempts to excuse the numerous deficiencies in Ermakov's and Burns's testing saying it would be difficult to conduct *in vivo* testing. ECF 71 at 15. There is no evidence they even attempted to perform this kind of testing, nor do they provide any explanation for how the testing is sufficiently similar to what would occur when the products are used on human nasal passages. *See* ECF 57 at 19-20; ECF 57-2 at ¶¶ 39, 42 (Dr. Amiji's testimony regarding differences between Trutek's testing and real life use of products). Similarly, Trutek offers no evidence to support its assertion that precision in applying the products "would be meaningless."³ ECF

³ Trutek also tries to distinguish its product as a cosmetic or "face mask," not a pharmaceutical. This is pure semantics. The products are liquid or gel, not a face

71 at 15. And just because Trutek tests the surface charge of its products on paper for quality control does not establish the protocol and tests performed by Ermakov and Burns are recognized as valid and reliable by the wider scientific community. There is no evidence Burns performed a “baseline” study on uncoated material; he reports only results for NasalGuard and NanoBio. ECF 71 at 17; ECF 57-5 at 5-6. While Burns ionized the test substrates, neither Burns or Trutek provides any evidence for why this procedure was appropriate. Finally, while Trutek asserts “Measurement of surface electrostatic charge is not new science,” it does not cite any supporting evidence or explain why this matters. ECF 71 at 10. BlueWillow does not dispute whether measurement of electrostatic charge is *possible*, only whether the Ermakov and Burns tests are reliable given the purpose for which they are used, *i.e.*, to demonstrate surface charge when applied to human nasal passages.

Nor has Trutek rebutted BlueWillow’s argument that the test results are not probative of any material fact related to infringement. ECF 57 at 24-25. Instead, Trutek mistakenly asserts that the motion to exclude stems from a “desire to deny that its product exhibit[s] an electrostatic charge,” (ECF 71 at 16) and the testing is relevant because the measurement of an electrostatic charge is probative to infringement (*id.* at 11-12). The ’802 patent claims require more than exhibiting an

mask. Trutek also asserts that its products use the ’802 patent technology (ECF 71 at 4), which the Court has identified as “pharmaceutical formulation.” ECF 53 at 8.

electrostatic charge. Trutek's testing does not establish that the measured charge is capable of electrostatically attracting and inhibiting particulate matter and thus, has no bearing on whether NanoBio Protect practices any element of the '802 patent claims. Likewise, the conclusion that NanoBio Protect and Nasal Guard exhibit a charge "of the same order of magnitude" is irrelevant; infringement is not assessed by comparing the accused product to the patentee's product. ECF 57 at 24.

For all of the foregoing reasons, including those provided in BlueWillow's Motion (ECF 57), Trutek has not demonstrated the reliability or relevance of the Burns and Ermakov testing. BlueWillow respectfully submits that the Burns and Ermakov testing and any testimony related thereto should be excluded.

Dated: May 30, 2023

Respectfully submitted

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CERTIFICATE OF SERVICE

I hereby certify that, on May 30, 2023, I filed the foregoing document and this Certificate of Service with the Court using the ECF system.

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